[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers.

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Provisional Patent Application 62/006,313 entitled "Chimeric Antigen Receptors Targeting CD-19" [HHS Ref. E-042-2014/0-US-01], and all related continuing and foreign patents/patent applications for the technology family, to Kite Pharma, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to: "All prophylactic and therapeutic uses for CD19-associated diseases, states and conditions in humans."

DATE: Only applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: lambertsond@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns an anti-CD19 chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of CD19-expressing cancers, including B cell malignancies.

CD19 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly cancers of B cell origin such as Non-Hodgkin's Leukemia (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). The anti-CD19 CARs of this technology contain (1) antigen recognition sequences that bind specifically to CD19 and (2) signaling domains that can activate the cytotoxic

functions of a T cell. The anti-CD19 CAR can be transduced into T cells that are harvested from a cancer patient; from there, T cells expressing the anti-CD19 CAR are selected, expanded and then be reintroduced into the patient. Once the anti-CD19 CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to CD19-expressing cancer cells through its antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404 within thirty (30) days from the date of this published notice.

Complete applications for a license in an appropriate field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: June 22, 2015

Richard U. Rodriguez, M.B.A.
Acting Director
Office of Technology Transfer
National Institutes of Health
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